IN THE UNITED STATES DISTRICT COUR THE COURT

IN AND FOR THE DISTRICT OF DELAWARE

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CHIESI USA, INC., CORNERSTONE BIOPHARMA, INC., and EKR THERAPEUTICS, LLC,	)	**Civil Action**
Plaintiffs,	)	
v.	)	
EXELA PHARMA SCIENCES, LLC, EXELA PHARMSCI, INC., and EXELA HOLDINGS, INC.,	)	
Defendants.	)	**No. 13-1275-GMS**

- - -

Wilmington, Delaware
Monday, June 15, 2015
9:30 a.m.
Markman Hearing

- - -

BEFORE: HONORABLE GREGORY M. SLEET, U.S.D.C.J.

APPEARANCES:

FRANCIS DiGIOVANNI, ESQ.
Drinker Biddle & Reath LLP
-and-
ANGUS CHEN, ESQ., and
MICHAEL W. HARKNESS, ESQ.
Frommer Lawrence & Haug LLP
(New York, NY)

Counsel for Plaintiffs

APPEARANCES CONTINUED:

BENJAMIN J. SCHLADWEILER, ESQ.
Ross Aronstam & Moritz LLP
-and-
JEFFREY D. BLAKE, ESQ.,
JEFFREY S. WARD, ESQ., and
WENDY M. WARD, ESQ.
Merchant & Gould
(Atlanta, GA and Madison WI)

Counsel for Defendants

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:32:01 **THE COURT: Good morning. Please take your seats, counsel.**

:32:06 **Mr. DiGiovanni.**

:32:08 **MR. DiGIOVANNI: Good morning, Your Honor. Frank DiGiovanni from Drinker Biddle & Reath representing plaintiff. My my co-counsel with me today, from Frommer, Lawrence & Haug, Angus Chen, who will be handling today's argument, and Michael Harkness. And in-house counsel for Chiesi USA is Michael Gordon.**

:32:34 **MR. GORDON: Good morning, Your Honor.**

:32:34 **THE COURT: Good morning.**

:32:34 **(Counsel respond "Good morning.")**

:32:38 **MR. DiGIOVANNI: We also have some summer associates from Frommer, Lawrence & Haug in the back.**

:32:42 **THE COURT: Counsel.**

:32:43 **MR. SCHLADWEILER: Good morning, Your Honor.**

:32:45 **Ben Schladweiler from Ross, Aronstam & Moritz on behalf of the Exela defendants. I am here today with Jeff Blake, Jeff Ward, and Wendy Ward, all from Merchant & Gould. Mr. Blake will be doing the presentation.**

:33:00 **THE COURT: Have you discussed how you want to handle the presentation?**

:33:04 **MR. CHEN: We have made a proposal that because there are only three terms, maybe one not disputed, to be honest, we proposed to defendants that we would proceed with all the terms in order, with the permission of the Court, and then defendants would respond.**

:33:16 **THE COURT: Is that acceptable?**

:33:17 **MR. BLAKE: Your Honor, that is fine with us, unless you have another preference.**

:33:20 **THE COURT: The first preference I have is to ask both of you why we would need to spend any time at all on "a pre-mixed aqueous solution."**

:33:34 **MR. CHEN: We agree with that, Your Honor.**

:33:36 **MR. BLAKE: Your Honor, may I address that for a moment?**

:33:39 **THE COURT: Sure.**

:33:39 **MR. BLAKE: I don't think we intended to spend any long period of time.**

:33:44 **THE COURT: I said any time.**

:33:46 **MR. BLAKE: I understand. Our submission is**

:33:48 **that since we weren't the party involved in the PTO, the**
:33:51 **parties in the PTO didn't necessarily focus on the correct**
:33:54 **parts of the patent.**
:33:54 **THE COURT: Without your erudition they would**
:33:59 **have strayed somehow? I am being a little facetious. But,**
:34:03 **come on. I have limited time, and wherever I can find time**
:34:06 **to save time, I take advantage of it.**
:34:11 **MR. BLAKE: Understood, Your Honor. If we could**
:34:12 **have just a minute to explain.**
:34:13 **There was another part of the patent that wasn't**
:34:15 **emphasized in front of the PTO.**
:34:20 **THE COURT: I will let you do that. I will let**
:34:23 **him go first, counsel.**
:34:25 **MR. BLAKE: Would you like me to start with the**
:34:27 **premixed aqueous.**
:34:29 **THE COURT: Go right ahead. I want to find out**
:34:35 **why I need to spend time talking about it.**
:34:35 **MR. BLAKE: Absolutely.**
:34:52 **I hope Your Honor can see that okay.**
:34:55 **THE COURT: Do you have slides?**
:34:56 **MR. BLAKE: I do. May I hand them up?**
:34:59 **THE COURT: That would be helpful, yes.**
:35:06 **MR. BLAKE: We are going to start on Slide 35.**
:35:08 **THE COURT: Thank you, counsel.**
:35:31 **MR. BLAKE: Your Honor, the reason we think we**

:35:33 **should address the pre-mixed limitation even in this light**
:35:36 **of what the PTO says, what's here in Column 3 of the patent,**
:35:40 **I think both parties have agreed, as Your Honor probably**
:35:42 **knows from the briefing, that since all the patents have the**
:35:45 **same specification, that we are just going to work off the**
:35:48 **'102 patent, which is the composition claims.**
:35:51 **Column 3 specifically defines what pre-mix**
:35:57 **means. Column 3 says, and it's in this quotes: "Pre-mix**
:36:01 **refers a pharmaceutical composition that does not require**
:36:03 **reconstitution or dilution before administration to a**
:36:06 **patient."**
:36:07 **This language in Column 3, it wasn't a focal**
:36:10 **point of the argument in front of the PTO. And that's why**
:36:15 **we think we need to address it, because this specific**
:36:17 **definition wasn't a focal point of the argument.**
:36:20 **And it's interesting, if you look at Column 3,**
:36:24 **it is a broader definition and it encompasses the definition**
:36:30 **that the PTO has. In the PTO, when they were looking at it,**
:36:35 **they focused on a different part of the patent, as did the**
:36:37 **parties there.**
:36:40 **Let me take a moment to explain that further.**
:36:43 **As Your Honor is aware, the Federal Circuit has**
:36:46 **stated that if you specifically define a term --**
:36:49 **THE COURT: I am aware of that, counsel.**
:36:51 **MR. BLAKE: Column 11 of the patent has what is**

referred to as an alternative aspects section. In this there, there is a narrower definition of pre-mix that restricts it to it's mixed at the point of manufacture. So you may wonder, how did we end up with a patent that's got a narrower definition and a broader definition? This is important, because it wasn't focused upon in front of the PTO.

What happened here is when the parties filed the provisional patent application that began the whole process, the spec in the provisional patent application was limited to this alternative aspect section of the patent. So the spec had a narrower definition when they filed the provisional.

A year later they filed a non-provisional, a year to the day later. When they did it, they added to the specification. And they added the language that is now in Column 3. They added a broader definition of pre-mix when they filed a non-provisional application than they started with, because they added additional embodiments. The stuff they added, that is what they are now claiming.

They are not claiming the alternative aspect section of it. They are claiming the broader definition and the use of this pre-mixed pharmaceutical composition in a situation where you have the nicardipine hydrochloride, and a co-solvent, tonicity agent, and a buffer.

:38:23 **If you look at, we have a tutorial here, to give**
:38:30 **a little bit of background, what happened with these**
:38:35 **products and how they came to be is, you used to have, what**
:38:38 **they originally had was a concentrated formulation of the**
:38:42 **product. It was in a vial. And at the point you want to**
:38:45 **give it to a patient, because it goes in intravenously, you**
:38:49 **inject it, before you give it to the patient, what you had**
:38:52 **to do is take it out of the vial, put it in this infusion**
:38:55 **bag, dilute it, reconstitute it, mix it up, it could take as**
:38:59 **much as two hours before you did that, and you could give to**
:39:03 **it a patient. That is what they referred to as the point of**
:39:05 **administration.**

:39:05 **These patents, all they did was say, well,**
:39:08 **instead of having it in the vial, let's just go ahead and**
:39:11 **make it in the bag so you don't have to reconstitute it**
:39:13 **before you give it to the patient at the point of**
:39:16 **administration.**

:39:17 **That's really all these patents are about, just**
:39:19 **taking what they knew. They knew they had to put it in the**
:39:22 **bag, and said, well, let's just broaden our product out, put**
:39:26 **it in the bag, while we are there maybe we can get some more**
:39:29 **patent life out of it.**

:39:31 **Nobody would say, in looking at "pre-mix" as**
:39:33 **they used it in this these patents, that it covers the point**
:39:36 **of administering. Our definition, which says it requires no**

:39:40 **further dilution, comes straight out of the patent. That**
:39:42 **doesn't cover point of administration because our definition**
:39:46 **specifically says you don't have to further dilute it before**
:39:52 **you give it to the patient, before you administer it.**
:39:55 **Our definition does not cover the point of**
:39:57 **administration.**
:39:59 **And I have got the blue box and the red box**
:40:02 **here. Our definition is broad enough to encompass the**
:40:06 **specific definition provided in Column 3. As a matter of**
:40:09 **fact, if we look back to what's in Column 3, our definition,**
:40:14 **word for word, comes from this language they added in the**
:40:17 **non-provisional application. And when they added it, that's**
:40:20 **what ultimately became the language in the patent.**
:40:25 **We would encompass the narrower definition of**
:40:28 **point of manufacture that's in that alternative aspect**
:40:32 **section. But there is no reason to limit the claim to that**
:40:36 **narrower definition. You have two competing definitions.**
:40:40 **And it is important that what happened is it was their**
:40:43 **choice. They had a narrower definition in the provisional**
:40:48 **application. They chose to broaden it when they filed a**
:40:50 **non-provisional.**
:40:51 **And it is also important that the way in which**
:40:53 **they broadened it is now the way in which they are claiming**
:40:56 **it. They are not claiming it in the way they claimed it in**
:41:00 **that alternate aspect section. They are using the broader**

definition, and that is what they are claiming if you look at the specification.

This wasn't a focal point in the PTO. That's why I am saying we should still address it here. I don't want to waste your time.

In addition, if you look back to the parties' respective constructions, I go back to Slide 34, there are other aspects of their limitation where Chiesi is trying to limit its own claim beyond just saying that pre-mix means it's got to be mixed from the point of manufacture. They are also adding all these limitations about how it has to be stable, the medical personnel have to be able to use it off the shelf, you've got to avoid contamination problems and dosage errors.

That's all in the background section of the patent. That's where that comes from, their attempts to limit the patents themselves.

This comes out of the background section, explaining, well, this is why we took our product, our original product that was in the vial, the concentrated form, and we ended up putting it into a bag to make it a more dilute product. They are saying, well, the alleged benefits of that are that it's stable, that you can use it off the shelf. These benefits come out of Column 1, I have got it here on Slide 40, if Your Honor is --

THE COURT: I have it.

MR. BLAKE: I apologize I if I am jumping around too much.

Here in Column 40, you look at it, it comes out of Column 1 of the patent, the background section, where they are saying, okay, this is the reason that we say -- when I say "we say," Chiesi says, the patentee, more accurately, says -- These are the reasons you need to make a bag instead of a concentrated vial product.

Now, all of these may be reasons why they chose to say that they wanted to change their product and they chose to say they wanted to get a patent, but those don't necessarily need to be read into the construction of a claim term, premixed, that, again, if I flip back to Slide 35, is directly defined in Column 3. The term is defined in Column 3, and none of these allegedly benefits are in the definition when they define it. They all come from the background section. They are what the patentee says is the appropriate reason to use it. When in Column 1 they discuss the background, that doesn't mean that those limitations should be restrictive of the claim itself.

The default here, the intrinsic evidence, if you look at it in its whole as to what happened, takes you back to what is a clear definition that's in Column 3 that encompasses the other discussion. And that's what we should

use.

Indeed, if you look at the prosecution history of the patent -- I am going to Slide 41 now -- the i4i case makes note of the fact that just because in your background section you may note the deficiencies in the prior art and you may state during prosecution that these are some of the deficiencies that we are trying to overcome, and they did say that in the prosecution, that doesn't mean that those terms should be incorporated into the construction.

Again, that gets back to -- this is, you know, we are bringing up some points that weren't necessarily considered fully by the PTO in our opinion. And we would like Your Honor to consider them.

I have already covered the middle point there about the non-provisional application, how this came to be.

I would note that it is interesting that Chiesi's limitation is essentially prosecution disclaimer arguments for their own patent claim. They are essentially saying we got this claim but we want to limit it.

If I could back to my slide here, in Slide 38, they are, as you can see, restricting it to this little bubble around the point of manufacture. And they are further restricting it by adding those other limitations about having to be stable and no dosage errors, things of that nature. That's not how the claim should be covered.

:45:28 **Everyone agrees that the claim, as far as it should be construed for pre-mix, should not be the point of administration. Our definition doesn't cover that. But, for instance, if there is a compounding pharmacy or some other pharmacy, that would be a pharmacy that after the product is manufactured might do the pre-mixing there before it's sent to be administered to a patient, the definition in Column 3 is broad enough to cover that, yet they are now saying it's not.**

And they are now saying, in addition to restricting it to the point of manufacture, our claim should be limited by all this other stuff about the product being stable, on the other side, the product being stable, the product being able to be used off the shelf without any concern about contamination problems or dosing errors. All these limiting formulations, limitations are a little bit out of the ordinary for a patentee with their own claim language, but particularly here, where you have an express definition in Column 3. And that's the one that Exela is working off of.

That's all that I really have on the pre-mix point, unless you have a question.

THE COURT: No. I -- I may be perhaps being somewhat obtuse. But, counsel, I am not seeing a Grand Canyon between you and the PTO, quite frankly, your proposed

definition and what the PTO says and ergo the plaintiff. You are both talking about, you and the PTO, that's what I am talking about, you are talking about a ready-to-use solution, you are talking about in essence a pre-mix, something that doesn't require reconstitution, as you suggested, in your language -- I think the PTO's definition contemplates that -- or dilution, for that matter.

And you are both in agreement before the point of administration, before the point of administration. I think perhaps where the difference may be -- I don't know, you tell me -- is the last clause, the last phrase, and is stable at room temperature for six months or longer.

Other than that, I don't see a lot of difference between what the PTO, its construction, and yours.

MR. BLAKE: The will only thing that I would say, whatever construction that we have, if it's not limited to that point of manufacture, I mean, what you have here -- here is the underlying issue. We are concerned about -- this is an invalidity-related argument. They want to add to the limitation so that if there is any prior art it's got to meet all these definitions of what pre-mix has to fulfill in the prior art.

THE COURT: I want you to put the plaintiffs' construction off to the side. And just talk to me about why I shouldn't accept the PTO's language.

:48:30 **MR. BLAKE: I think, at the end of the day,**
:48:33 **there is not a huge chasm between the two. But I don't feel**
:48:38 **like it should be restricted any more as far as the six**
:48:42 **months, because the definition doesn't say that.**
:48:43 **THE COURT: That's what I was asking, in the**
:48:47 **form of perhaps not a real interrogatory but a question,**
:48:52 **whether that was the essential difference -- different**
:48:57 **words, admittedly -- between Exela and the PTO, whether that**
:49:01 **clause is the essential difference.**
:49:03 **MR. BLAKE: That is essentially the difference.**
:49:05 **It shouldn't be restricted to that time of six months.**
:49:07 **THE COURT: Assuming that, let me say, for**
:49:10 **hypothetical reasons, were I to accept that, plaintiffs tend**
:49:14 **to agree. Mr. Chen said at the beginning, Judge, take the**
:49:18 **PTO's definition.**
:49:20 **MR. CHEN: Yes, Your Honor. We are okay with**
:49:22 **that.**
:49:22 **THE COURT: I don't know why there is not an**
:49:26 **opportunity here for agreement between the parties on how**
:49:28 **the Court should construe this thing.**
:49:31 **MR. BLAKE: Can I confer with co-counsel?**
:49:34 **THE COURT: Please.**
:49:35 **(Counsel confer.)**
:49:36 **THE COURT: Mr. Blake, you may want to confer**
:50:06 **with Mr. Chen, based on that conference you just had with**

your colleague. It's fine with me. I would just as soon sit here. If there is an opportunity, you both don't have to worry about your clients having to pay for you to do this all over again after the Federal Circuit takes after me. Go ahead.

MR. BLAKE: The biggest point for us is that point of manufacture restriction. If we can meet and work something out on that point...

THE COURT: Why don't you talk to Mr. Chen and see if there is a potential for a further conversation.

MR. BLAKE: Would you like us to do that now?

THE COURT: I would, yes, sir.

MR. BLAKE: Your Honor, we don't have an agreement. I will say that. What we are willing to do is live with the PTO's definition, if you read through it, up until the point it says "at the point of manufacture," period. The part we can't agree to is "and is stable for six months."

Let me explain what our concern is.

Our concern is that you are reading in, importing that stability into this term premixed. And first of all, how you are going end up defining "is stable," that is not something that the parties have ultimately briefed, how that "is stable" should be construed. That leaves that open. Also, it is just an importation into the term of

something that is not part of it.

THE COURT: Where do you think the PTO got that limitation from?

MR. BLAKE: I think, looking at the patent, because the other parts of the claim discuss "is stable." You look at that time patent language and the patent specification, it discusses the stability over time. But it doesn't discuss it in the context of defining premix.

THE COURT: Okay. All right. Thank you.

Mr. Chen, there is your -- I hope we have narrowed the focus sufficiently for you to be able to really laser in on your argument.

MR. CHEN: We do, and thank the Court for helping facilitate that process.

THE COURT: Why don't you take the podium.

MR. CHEN: Your Honor, may I approach.

THE COURT: Yes, sir. Mr. Buckson will take that from you.

MR. CHEN: Your Honor, may it please the Court, we kind of jumped into it. My name is Angus Chen of the law firm of Frommer, Lawrence & Haug. We thank the Court for your assistant in some resolution of the claim at issue.

As to the second half, to answer Your Honor'S questions, the PTO did consider we think all the arguments that basically the parties set forth in its briefing. Where

:55:19 1 **the PTO got the stability issue is they called it the**
:55:24 2 **hallmark of the invention. The whole goal of these premix**
:55:26 3 **compositions is not just to have this premix composition but**
:55:29 4 **to have one that is really stable.**
:55:31 5 **THE COURT: That is not my first dance with**
:55:33 6 **pre-mix and stability, as you might imagine. I get it.**
:55:40 7 **That's for Mr. Blake's benefit.**
:55:42 8 **MR. CHEN: The term stable is defined in the**
:55:44 9 **patent, as the PTO noted. It is in Column 3, Lines 51 to**
:55:50 10 **53. It refers to the overall stability of the composition.**
:55:53 11 **It is the state or condition that is suitable for**
:55:56 12 **administration to a patient.**
:56:00 13 **That's different than the claim limitation that**
:56:02 14 **talked about the potency of the drug only, and the total**
:56:06 15 **purity, this other aspect of stability to that**
:56:07 16 **pharmaceutical composition that make it suitable for**
:56:10 17 **administration.**
:56:10 18 **In our view, we agree with Your Honor that we**
:56:16 19 **should stick to what the PTO considered, and we see no**
:56:19 20 **reason to depart from that.**
:56:20 21 **THE COURT: I am inclined in that direction. I**
:56:23 22 **want to be perfectly candid. I will keep a little of an**
:56:27 23 **open mind on it as I leave the Bench. The nice thing about**
:56:34 24 **practicing before me is you still have no de novo review,**
:56:40 25 **because I am not doing Teva-related fact-findings, at least**

:56:44 **I have not been asked to do that so far.**

:56:46 **Okay. Let's go to the next.**

:56:49 **MR. CHEN: Thank you, Your Honor.**

:56:50 **Then I will jumped to Slide 21. It's the two**
:56:56 **terms "buffer" and also "buffer in an amount to maintain pH**
:57:00 **from about 3.6 to about 4.7."**

:57:05 **Slide 22 just gives a survey of the claims in**
:57:09 **which these two terms are found. For all intents and**
:57:12 **purposes, I think the dispute is the same between those with**
:57:15 **two terms. I really don't think there is a fundamental**
:57:19 **difference.**

:57:20 **Our construction is taken from a definitional**
:57:22 **phrase in the patent that says, "a system capable of**
:57:25 **maintaining the pH within an optimal pH range," and for the**
:57:30 **term that has the about, the numerical range, we just added**
:57:35 **in the numerical range.**

:57:38 **Exela has a construction where we believe they**
:57:41 **are adding words to the construction that aren't even found**
:57:45 **in the patent, actually. That's why I am making the**
:57:47 **distinction between adding an import. It is not even an**
:57:52 **import from our perspective. It is just purely being added**
:57:54 **to the claim construction. That is the separate and**
:57:58 **distinct phrase, that the buffer has to be separate and**
:58:01 **distinct from a certain list of ingredients, according to**
:58:04 **Exela.**

:58:04 **The second part that we believe is imported, which is taken from only some examples from the patent, is the phrase "has sufficient buffering capacity to maintain an optimal pH range throughout the shelf-life of the product."**

:58:17 **Just to show you the support for our claim construction, that is taken from the '102 patent, Column 3, this is in Slide 24, where the patent describes a buffer that is capable of obtaining maintaining a pH within an optical pH range. That is our construction. We tried to stay true to the specification.**

:58:35 **We also, just to show you some support, I am not sure this is really in dispute, based on Exela's answering brief, I note on Page 12, No. 3, that they admitted in their answering brief that a buffer can be made of more than one component.**

:58:51 **The other aspects of our claim construction are taken from other parts of the patent where it talks about buffer can be a system, meaning it can be more than one agent that comes together and creates a buffer system.**

:59:03 **So Slide 26, this is exactly what I said before. Nowhere do the patents talk about separate and distinct. Those words are just not found in the patent at all. Throughout the shelf-life of the product, that is coming straight from the language where the qualifier is in that sentence that expressly says, "in some embodiments," "in**

:59:25 1 **some examples."**

:59:26 2 **What is really telling to us is that in Exela's**
:59:29 3 **Paragraph 4 notice letter, I think Your Honor is very**
:59:32 4 **familiar with that, after all the Hatch-Waxman cases you**
:59:35 5 **have done, they have to send a notice letter to the patentee**
:59:37 6 **in advance of litigation and say, hey, we filed a Paragraph**
:59:41 7 **4, and here's our factual and legal bases for why think the**
:59:46 8 **patent is either noninfringed or invalid.**

:59:48 9 **They sent two different notice letters for the**
:59:50 10 **four the different patents. In both notice letters they**
:59:52 11 **defined the term buffer. In that definition, they didn't**
:59:56 12 **find it to include separate and distinct, that phrase. In**
:59:59 13 **other words, they didn't say it has to be separate and**
:00:01 14 **distinct from a pH adjuster and all the other ingredients.**

:00:04 15 **What they said was these constructions that they**
:00:07 16 **offered in the notice letter are consistent with the**
:00:10 17 **specification and how a person of ordinary skill in the art**
:00:13 18 **understands it.**

:00:14 19 **In our view, to now insert the words "separate**
:00:17 20 **and distinct" is really just a litigation-driven argument to**
:00:20 21 **presumably attempt to create a noninfringement argument.**

:00:23 22 **Now, the reason why we think Exela's separate**
:00:27 23 **and distinct phraseology is wrong is because the patents**
:00:32 24 **expressly teach you that an ingredient can serve as both a**
:00:36 25 **buffer and other functions, like a pH adjuster.**

:00:40 **For example, the patent has a listing in Columns**
:00:44 **4 and 5, first it says a buffer can be acids and salts of**
:00:49 **something called citric. Then the next page it says, well,**
:00:55 **may pH adjusters can be citric acid or sodium citrate.**
:00:58 **We had an expert declaration explaining how**
:01:01 **those are the same compounds, basically.**
:01:05 **Also, the provisional application, that served**
:01:08 **as the provisional before the patents in suit were --**
:01:11 **THE COURT: You don't maintain that resort needs**
:01:14 **to be made by the Court to the expert declarations, do you?**
:01:18 **MR. CHEN: Only to the extent Your Honor deems**
:01:19 **it necessary to fill in any gaps.**
:01:21 **THE COURT: I just want, in fairness to the**
:01:23 **other side, for them to understand that I don't feel the**
:01:27 **need to refer to the expert declarations. I don't know if**
:01:32 **there is a counter-declaration or not.**
:01:34 **MR. CHEN: There is not on this term.**
:01:36 **MR. BLAKE: There is not. We don't think it is**
:01:37 **necessary.**
:01:37 **THE COURT: I don't, either. You need not be**
:01:40 **concerned, at least at this point, about going outside the**
:01:44 **intrinsic record in that way.**
:01:46 **MR. CHEN: Thank you, Your Honor.**
:01:48 **The provisional application to the patents in**
:01:50 **suit also expressly state, that is the second bullet there,**

:01:53 **that buffering agents are used to adjust the pH. There is**
:01:56 **an interrelationship here and there is no basis to create a**
:01:59 **wall, so to speak, and say a buffer should be separate and**
:02:03 **distinct from the pH adjuster.**
:02:06 **Exela relies heavily on a patent that is**
:02:09 **referenced in the patents in suit. It's called the '405**
:02:12 **patent. That patent also is consistent with our patent and**
:02:15 **how a person of ordinary skill in the art would understand**
:02:19 **the buffer term, and says that a buffer can include pH**
:02:23 **adjusters.**
:02:24 **So the '405 patent in the first callout says**
:02:27 **most preferably, the buffer is, and I am jumping ahead, for**
:02:31 **example, citric acid plus sodium hydroxide. Both of those**
:02:35 **are pH adjusters as well.**
:02:38 **So, actually, I think Exela recognizes that when**
:02:41 **it calls out a similar quote in their brief, I believe it's**
:02:45 **in their opening brief at Page 16.**
:02:48 **Now, as I understand it, the main authority that**
:02:53 **Exela relies on is the Becton case, and sort of what they**
:02:57 **call the structure of the claims. That case, we think, is**
:03:01 **very distinguishable. The Federal Circuit subsequently did**
:03:05 **distinguish that case. In that case, it had to do with a**
:03:10 **similar dispute, whether two components could serve as a**
:03:13 **single claim limitation. There it did not make sense. It**
:03:17 **was a physical impossibility and nonsensical for the two**

components to serve one function. That is clearly not the case here from our own specification, as well as the '405 patent that Exela relies on.

The Federal Circuit explained that in a subsequent case call Powell that the parties both referred to in their briefs, and found that, In general, two claim terms actually can be satisfied by one component and don't necessarily require separate structures.

There are other cases following that line of thought cited on this slide and in our briefs, Linear Tech. v. Intellectual Property.

That is the separate and distinct part.

If we move over to the sufficient buffer capacity in an amount to maintain the desired pH range throughout the shelf life of the product, that we believe is a clear importation. Not to be too dramatic, but borrowing a phrase from the Federal Circuit, it is a cardinal sin of the patent law to import a limitation from some advance.

The phrase that Exela makes, made through in this callout, it is very important to recognize I think the first qualifier, the first three words of that sentence, in some embodiments, some examples, a buffer has sufficient buffering capacity to maintain the desired pH throughout the shelf life, not all. And there is no disavowal in the patents, in the file history or anything to that effect,

:04:40 1 **that would justify narrowing the limitation to throughout**
:04:43 2 **the shelf life of the product.**
:04:45 3 **In fact, what the patents teach, as we discussed**
:04:47 4 **in the premix term, that the patents teach compositions that**
:04:52 5 **are stable for six months or longer.**
:04:54 6 **Clearly, there is no mandate, no requirement**
:04:56 7 **that the pH be maintained throughout the whole shelf life.**
:05:00 8 **And so we believe there is no justification for that**
:05:06 9 **limitation.**
:05:07 10 **From my perspective, that's all I had on the**
:05:09 11 **buffer term, unless Your Honor had questions, I can move on.**
:05:13 12 **THE COURT: I don't.**
:05:13 13 **MR. CHEN: Thank you.**
:05:14 14 **The last term, this is one of the terms where,**
:05:18 15 **honestly, Your Honor, I am not really sure there is a**
:05:20 16 **dispute.**
:05:20 17 **THE COURT: If there is not...**
:05:25 18 **Is there a dispute?**
:05:26 19 **MR. BLAKE: Our belief, there is no need to have**
:05:28 20 **a construction.**
:05:29 21 **THE COURT: I know. So I am sure, Mr. Chen, you**
:05:34 22 **understand that position.**
:05:35 23 **MR. CHEN: Maybe I could articulate why I think**
:05:37 24 **there is no dispute.**
:05:39 25 **THE COURT: Why don't you do that.**

MR. CHEN: And give Mr. Blake a chance to respond.

THE COURT: Go ahead.

MR. CHEN: Our construction really just explains that one year and three months, meaning what they say, is the full term. The genesis of the dispute, Your Honor, is, as you know from the IPR, there is a related litigation in New Jersey against another generic. We started the Markman process there a little early. We had a Markman hearing in mid-May. No decision yet --

THE COURT: Who is the Judge?

MR. CHEN: Judge Hillman. We obviously will advise you if and when he comes out with the claim construction to the extent you want to consider it.

What happened there was the generic --

THE COURT: I think it is good thing for the parties to advise District Courts who are dealing with the same issue, that is a problem, when we have disparate constructions floating around out there in the universe. I have great respect for Judge Hillman. He knows what he is doing.

MR. CHEN: So we obviously will apprise you of the status of that Markman.

What happened was, the generic in that case consisted that one year -- I will focus on the one-year

:06:53 **term, because effectively the dispute is the same -- that it**
:06:56 **should be synonymous with what we call accelerated condition**
:06:59 **testing in the pharmaceutical industry. That's testing that**
:07:03 **sort of models full-term testing. And it models that by**
:07:08 **creating stress conditions, elevated temperatures, like 40**
:07:12 **to 45 degrees Celsius, instead of room temperature, which is**
:07:15 **25 degrees Celsius.**
:07:17 **It also changes the humidity. It is a way to,**
:07:21 **as you might guess, accelerate the stability testing to sort**
:07:24 **of make a hypothesis about what actually happened when you**
:07:27 **put the drug up on stability for a full one year.**
:07:30 **Now, the source for our words full term is from**
:07:37 **actually a reference cited in the specification, which we**
:07:40 **understand the Federal Circuit treats as intrinsic evidence.**
:07:43 **It is called Connors. It's cited on Column 15, Lines 7**
:07:56 **through 9 of the patent, where it talks about stability**
:07:59 **testing being done for full term and needs construction**
:08:03 **under accelerated conditions. That is really where we are**
:08:06 **coming from with respect to using the use of the word full**
:08:09 **term. At least preliminarily at the Markman hearing, Judge**
:08:14 **Hillman seemed to agree with us that full term was okay to**
:08:18 **use.**
:08:18 **So that's really where we are coming from.**
:08:21 **My main point is nowhere do the patents actually**
:08:24 **define accelerated conditions to be synonymous with one year**

or three months at room temperature. In fact, they are very different sets of conditions, as evidence in Example 6 and Table 4.

I think where the parties have agreement is, they put in an expert declaration to this effect, too, in their answering brief, that the accelerated conditions are used to hypothesized a model of what you will see at room temperature.

I don't have a problem, as defendants said in their briefing, if they want to, during the liability phase, present some data under accelerated conditions, and say, Your Honor, we think this demonstrates one year at room temperature, I am okay with that, and we will assess the weight of the evidence at that juncture.

What I am trying to make clear is that one year full term at room temperature is not synonymous with accelerated conditions.

THE COURT: Fair enough. I don't know if this is going to be helpful to the parties or not, but you just indicated, seemed to be comfortable with full term in the opposite direction. This highlights and illustrates part of the issue. Reasonable people can disagree. Even judges can be reasonable.

MR. CHEN: In fairness to Judge Hillman, that was only his preliminary views.

:09:46 **THE COURT: This is my preliminary view. I came**
:09:48 **out here for a reason.**
:09:52 **MR. CHEN: Thank you, Your Honor.**
:09:54 **MR. BLAKE: Your Honor, do you have a preference**
:10:01 **whether I jump into buffer or one year full term?**
:10:05 **THE COURT: Whatever you feel most comfortable**
:10:07 **with.**
:10:11 **MR. BLAKE: Why don't you put up our slides.**
:10:12 **Let's start with the buffer. Really, that's the**
:10:14 **key term here. Let me just provide some background.**
:10:19 **As Your Honor knows, they went from having this**
:10:22 **vial product to this premixed bag and they say, well, you**
:10:27 **know, let's try to get some patents on the pre-mixed bag**
:10:30 **product.**
:10:30 **A focus of what they say in the patents,**
:10:33 **throughout the patents, is that, when they are describing --**
:10:38 **I am here on my Slide 3, just to orient you, if you look at**
:10:49 **the quote here from Column 1. When they are just starting**
:10:52 **to summarize what they are doing here in going to the**
:10:54 **pre-mixed bag product, in the latter part of that sentence,**
:10:58 **where they say the ready-to-use-pharmaceutical compositions**
:11:00 **with a buffered pH are stable at room temperature for at**
:11:04 **least one year.**
:11:05 **The focus of the patent to them when they got**
:11:07 **these bags is what they say is that this buffered pH and**

that the buffer is, in their view, essential to these pharmaceutical compositions.

Now, why is that important and why are we all here? Because in Exela's view, to have a bag product, the buffer is not essential. We found a different way to manufacture the product and we don't have a buffer.

And they say you got to have a buffer for these products and that's the focus of the patents.

We found a different way, actually, a way that's kind of discussed in that '405 patent -- that is intrinsic evidence, but there is also prior art. Our way of manufacturing the product doesn't have a buffer. And now they are reading the patent claim and how they define buffer in a way that they can try to cover our product that doesn't have a buffer by saying, well, you can have other components that have multiple functions. And that's the effort to say we still infringe when we designed around these patents. We were aware of them, and we designed around them to take the buffer out. We had a vial product, one of those previous vial products, and we decided likewise to make a bag product. When we made our bag, we took the buffer out because of these patents.

THE COURT: Let me make sure I understand your proposal. You propose within annual optimal pH range. That would cover potentially your invention.

MR. BLAKE: They are going to argue that it does. I wouldn't agree with that. Let me tell you why they are going to argue that.

They are going to say -- I don't want to speak too much Mr. Chen -- this is, as I understand it, that we have hydrochloric acid in our product, which is in there as what you refer to as a pH adjuster. I will cover a little more the difference between buffer and pH adjusters at a high level. At a high level, they are opposite things. A buffer maintains a pH, you are probably familiar with this, even more so than me.

THE COURT: Not more so. But I am familiar with it.

MR. BLAKE: A buffer maintains the pH. A pH adjuster is designed to quickly change the pH, as they defined them in the patent. They defined them in the patent that way. Those are opposite purposes. My understanding is there is going to be an argument as to whether or not that hydrochloride acid can serve both functions in our products. And we are going to hotly dispute, even if they get their construction, we are going to hotly dispute that fact.

THE COURT: I would say still a fact capable of being hotly disputed, hypothetically speaking, were I to accept their proposal.

MR. BLAKE: Definitely.

:13:41 **But now I am going to move up to Slide 8 of our**
:13:45 **presentation. Let's talk about our construction. And it**
:13:56 **does have two parts. So I will break it down into two**
:13:59 **questions that I will cover sequentially.**
:14:01 **The first is that the construction would be that**
:14:04 **the buffer is a separate and distinct component of the**
:14:10 **composition. The intrinsic evidence bears that out. If you**
:14:15 **look at the claims, if you look at all the embodiments**
:14:18 **disclosed in the specification, and if you look at the**
:14:22 **prosecution history -- and I will go through each in some**
:14:25 **detail -- all of them discuss the buffer as a separate and**
:14:29 **distinct component.**
:14:35 **In each situation, we will see, as we walk**
:14:38 **through it, that's how it's defined consistently throughout.**
:14:41 **The second question is the second part of what**
:14:44 **you see here, the last three lines of our construction,**
:14:48 **where it says, it has sufficient buffering capacity to**
:14:51 **maintain an optimal pH range throughout the shelf life.**
:14:56 **That buffering capacity, which is effectively**
:14:58 **what a buffer does, it is kind of common sense, a buffer has**
:15:02 **to have buffering capacity to do its job. That does come**
:15:04 **out of the patent. It is not just from some embodiment. It**
:15:07 **is from all the embodiments. We will get to that in a**
:15:10 **moment.**
:15:10 **Let me start with the first question. Moving to**

:15:14 **our Slide 9, where we laid out the two questions. Let me**
:15:19 **start with the first question of whether the buffer has to**
:15:22 **be separate and distinct.**
:15:24 **On Slide 10, I have put up the first two claims**
:15:27 **of the '102 patent. We have color-coded them a little bit**
:15:35 **to make the point that what you see here are separately**
:15:40 **listed components of the composition. The active**
:15:46 **pharmaceutical excipient which the nicardipine hydrochloride**
:15:50 **there in blue, a tonicity agent there in yellow, there is**
:15:53 **the buffer in green.**
:15:56 **And those are the three components that are**
:15:58 **listed in the composition in Claim 1.**
:16:00 **If you look at Claim 2, of course, which would**
:16:02 **incorporate the three components found in Claim 1, Claim 2**
:16:06 **adds the pH adjuster that is the focus of a lot of our talk.**
:16:11 **It adds a separate component in this claim.**
:16:14 **Moving to Slide 11, as Mr. Chen noted a moment**
:16:19 **ago, we do focus on the Becton Dickinson case, which states**
:16:23 **the point that if you clearly list components separately in**
:16:28 **the claim language, there is an implication, according to**
:16:32 **the Federal Circuit, that they are distinct components. And**
:16:36 **that's how they were claimed. That's how you chose to do it**
:16:39 **and that's how they were claimed.**
:16:41 **Mr. Chen argues, in that case it was an**
:16:44 **impossibility. It would have been nonsensical to combine**

them. And the later Powell case says you don't always have to follow that rule.

This fits within the Becton Dickinson framework here because of the difference between what a buffer and what a pH adjuster is. They can't do the same thing. One is designed to maintain the pH. The other was designed to change the pH. Buffers maintain. PH adjuster the pH.

It is nonsensical to think of one component doing the same thing when you use it in a formulation.

Now, the patentees will say, we, citric can be a buffer, citric acid can be a pH adjuster. Those are, citric acid is one part of a citrate buffer.

Well, respectfully, that's true. That's what the patents says. But it depends on how you are using it in the formulation. You can use a citrate buffer in one instance in specific factual circumstances to be a buffer in the way you are using it. You can use citric acid by adding a few drops to a formulation to change the pH. That doesn't mean what is in the particular formulation that is performing both functions at the same time.

It's still identified as a separate component. How you are using it is one question. Whether or not the buffer is a separate component, that's the question you consider in looking at a formulation at the infringement stage. But how the patent defines a buffer and a pH

adjuster is what is important here. That is the intrinsic evidence. When you look at it carefully, the intrinsic evidence says they are separate things.

So let me move to the spec, the specification, and look further at what it says. I am now on my Slide 12.

Here in Column 2, the patent is disclosing the pharmaceutical composition, and it says the disclosure relates to and it separately identifies the nicardipine, the tonicity agent, and the buffer. Just the way the claim, separate Claim 1 we saw a moment ago, as I flip back to it, separately identified the three of them, the specification here in Claim 2 separately identifies the three of them.

Now, if we go on to our Slide 13, another part of the specification, this comes out of Column 4 of the patent. And it says -- this is where the buffers are specifically discussed in Column 4. It says the buffers suitable for use in these compositions include pharmaceutically acceptable salts and acids -- that's how you make a buffer system -- and it defines what you mean by pharmaceutically acceptable. It's used herein in the sense of being compatible with the other ingredients in the formulation.

So what is it saying? It's saying that you have a pharmaceutically acceptable salt and acid, that makes a buffer, that is compatible with the other ingredients in the

formulation. It's separate from the other ingredients but it has to be compatible with them.

If we look to Slide 14, there is a table, there are a lot of different embodiments of compositions that are disclosed in the '102 patent. But they share one thing in common. They all have a separately listed buffer. And Table 1 nicely summarizes that. If you look to Table 1, it's got a lot of different possible disclosures here. In discussing it, it lists the active ingredient, the tonicity agent, the buffer, the cosolvent. The buffer is separately listed again. This is by design, because when they came up with this patent, they thought of the buffer as a separately listed component. And a separate component is how they treated it as they were drafting the entirety of the specification.

Slide 15, there are a number of different methods of manufacture disclosed in the specification. This is Column 2, the first time the patent discloses manufacturing the compositions. And it discloses it. It says, when your making these premixed pharmaceutical compositions, what are you making? You are making a composition that comprises the nicardipine hydrochloride in a solution that has one or more tonicity agents, it has a buffer, and it optionally has a cosolvent. And if you look down to that last line of the quote here on Slide 15, it

says there is a pH adjuster that can be added.

Again, when you are discussing the methods of making this, you are discussing all these different components that go into what ultimately becomes the solution.

And I will go to Slide 16. It references, and I would encourage Your Honor to take a look at it, Column 8, 32, to 9, 32 of the patent. It is a whole column, I couldn't get it on the slide. There are a number of different embodiments for how to make this listed. And if you read them, you will see that all of them separately discuss adding the buffer in. Usually, it's citric acid that is added in with an anion like sodium hydroxide that ends up making the buffer system. In the way it is used in this situation, they are separately adding a component in to make a buffer.

The patent says it doesn't matter what order you put the components into the solution, you will see that they are put in a lot of various orders in the different embodiments. What is key is that all of them have a separate buffer component that is added to form a composition.

Even earlier, in premixed, we were discussing this alternative aspects section of the patent, even there, in the alternative aspects section, when we are talking

about buffers, it is consistent. I am looking at my Slide 17, which refers to Column 11, even there, discussing the alternative aspect of the invention, it says that you have a composition comprised of nicardipine piano, referred to as the cardiac medication, a cosolvent, a complexing agent and a buffering agent.

It's a separate component because that's the way they thought of it when they drafted their patents.

Mr. Chen noted earlier the '405 patent in one of his slides. The '405 patent is intrinsic evidence as it says here on our Slide 18. It was referenced in Column 2 of the patent and the patent says it incorporates by reference everything that's discussed in other patents that are mentioned in the '102 patent. The Federal Circuit has said that if you incorporate by reference, that makes it intrinsic evidence.

We look to the '405 patent, which covers that prior art vial formulation. The '405 patent additionally has the same type of layout. It discusses a composition with nicardipine, a non-chloride compound to make it isotonic, that is the tonicity agent that is seen in the '102 patent, in Element (c) it has a buffer, and in Element (d) it has an aqueous vehicle. That is interesting that in exactly the same way, in intrinsic evidence the '405 patent is separately listing the buffer as an additional component.

:24:52 **But the key disclosure in the '405 patent is**
:24:57 **actually what happens with these Examples A and B. They are**
:25:01 **very interesting because Examples A and B in this '405**
:25:06 **patent talk about formulations that do not have a buffer.**
:25:10 **And the patent says, okay, if we look at these examples,**
:25:15 **they refer to them as prior art to the '405 patent, it says**
:25:19 **we have got these non-buffered formulations and when you**
:25:23 **test them they are unsatisfactory, when you put together**
:25:25 **something that is without a buffer because you have what is**
:25:28 **referred to as lack of pH control.**
:25:30 **There is nothing in there to keep the pH from**
:25:32 **getting outside a certain range and if it gets outside the**
:25:35 **certain range you have manufacturing problems or you have**
:25:38 **stability problems.**
:25:42 **There is a table, Table 1 in the '405 patent,**
:25:45 **cited here on our Slide 20, the table refers to Examples A**
:25:53 **and B. You will see, the heading says these are**
:25:57 **unsatisfactory formulations. They do not have a buffer in**
:26:00 **them. They can't control the pH. They are unsatisfactory.**
:26:04 **An interesting side note, if you look at these**
:26:07 **ingredients in Example A, nicardipine, sodium chloride,**
:26:13 **hydrochloric acid, water for injection, in Example A you**
:26:18 **will see there is no sorbitol, it is the first and last two**
:26:21 **ingredients, those there the same ingredients in Exela's**
:26:24 **composition that is accused of infringement. What they**

called in this -- not Chiesi, but the patentee in this '405 patent -- called an unsatisfactory composition, because it doesn't have a buffer, has the same ingredients in different quantities but the same ingredients is what Exela now says doesn't infringe the patents in suits.

That is notable because if you look at what the '405 says next, the '405 said take that formulation without a buffer, it has got problems, look over on our Slide 21, there is a cite here from Column 1, I think that might not be Column 1 -- it might be Column 6 -- I believe our slide on 21 incorrect. I think it's Column 6.

What it says is important. It says when you are having these problems because of unsatisfactory formulation, to overcome them you add a dilute buffer solution to Example B.

Let me go back to that previous slide. Here, it is unsatisfactory, it doesn't have a buffer in the '405 patent. The '405 patent says we can solve that by adding a buffer. It is a separate component. Add it in separately, that will solve your problems.

Again, this is important because the patents in suit incorporate by reference the '405 patent. It is intrinsic evidence of how you would think of a buffer.

THE COURT: I am with you.

MR. BLAKE: Making sure.

I have handled the '405 patent.

Let me step back to the specification to make one or two other points and respond to some of Mr. Chen's arguments, because I think primarily what you are going to hear is a couple things. One is that a component has multiple functions in the formulation. One thing, to be a pH adjuster and a buffer is the most pertinent example. Number one, I would say, the common scientific, when they put in the non-provisional application, and that became ultimately the common specification of all these patents, it separately defines these different components. There are separate patents that define the pH adjuster, the tonicity agents, the cosolvents, there is one for the buffer, they are all separately defined.

If we turn to our Slide 23, it's important to note the difference between the buffer and the pH adjuster as it is defined in the patents. The spec teaches in Column 4 of the '102 patent that the buffer maintains the pH range. It also teaches that a buffer has to be there in a particular concentration level to main that pH range. In other words, you got to have enough of the buffer there to be effective for its purpose. If you want to be able to maintain it, you have got to have enough there.

THE COURT: A novel concept.

MR. BLAKE: These concentration ranges are

:29:19 **important. You got to have a certain amount.**

:29:22 **Look to the next column, Column 5, that is where**
:29:24 **the pH adjuster is defined, our Slide 24 kind of summarizes**
:29:28 **what is said about the pH adjuster. It is different than a**
:29:32 **buffer. It is the polar opposite. It is not maintaining**
:29:36 **the pH, as its name implies, it's adjusting the pH.**

:29:41 **Whereas the patentee in this case said a buffer**
:29:44 **is needed for pH control of these products so you can**
:29:47 **manufacture them and maintain their stability appropriately.**
:29:50 **The pH adjuster is noted in Column 5 as being added on an**
:29:56 **as-needed basis. The reason for that, as you think about**
:29:59 **it, is how you make the products. You put the buffer in,**
:30:02 **you put the active ingredient in. And you may have to add a**
:30:06 **few drops of pH adjuster to end up with the pH that you want**
:30:09 **the product to stay at. Sometimes you need that, sometimes**
:30:12 **you don't. You it is used on an as-needed basis.**

:30:17 **Whereas the buffer, s there for a particular**
:30:20 **purpose. It's always needed in these products because you**
:30:23 **have got to have that pH control to maintain stability and**
:30:26 **to be able to manufacture it appropriately.**

:30:28 **I have covered can the fact that it changes the**
:30:33 **PI, it is added only as an as-needed basis.**

:30:38 **There is no concentration levels for the pH**
:30:41 **levels the way there were for the buffer because you only**
:30:44 **need a few droplets of it. And the buffer you need a**

:30:47 **certain concentration for it to do its job. With the pH it**
:30:51 **is a distinguishing point of how the patent uses a buffer**
:30:53 **versus a pH adjuster. Simply put, the patents treat them as**
:30:57 **a different thing.**
:31:02 **A point raised in the briefing, a separate point**
:31:06 **here that is raised in the briefing by Quiesi is that the**
:31:10 **provisional application for what ultimately became the**
:31:16 **patents had this sentence in there, I am looking at our**
:31:19 **Slide 25, the sentence said buffering agents are used to**
:31:23 **adjust the pH of the pharmaceutical formulation. Again,**
:31:27 **they are saying that the buffering agents and pH adjusters**
:31:29 **are conflated.**
:31:34 **I think the provisional application, if you look**
:31:36 **at it in context, it didn't say this but it loosely used the**
:31:41 **language and the patentee decided that they were using it**
:31:43 **incorrectly. And I will tell you how I think that.**
:31:47 **One, the provisional patent application, it**
:31:49 **doesn't define a pH adjuster. It doesn't say what a pH**
:31:53 **adjuster is. It has the statement about buffering agents**
:31:56 **being used to adjust the pH.**
:32:00 **If we go to Slide 26, when they filed a year**
:32:08 **later the non-provisional application, two interesting**
:32:12 **changes happened. One, they took out this sentence about**
:32:16 **buffering agents being used to adjust the pH. And they**
:32:22 **added the definition of a pH adjuster that you now see in**

the common specification of the patents. And I think that those two changes were made in the non-provisional application because they realized that there was some loose language in that provisional application and really truly the buffering agent is not adjusting the pH. That's what a pH adjuster does. So they essentially changed the specification that became what's in the patents by taking out this incorrect sentence and adding a definition for a pH adjuster and called it a pH adjuster, and what it does is it adjusts the pH.

I don't think that this is any evidence that the buffer is not a separate component. In fact, I think it supports the fact that when you look at it, this sentence supports the fact that the buffer is a separate component because they chose the take it out. Wait a minute, let's be clear. A pH adjuster does one thing, a buffer does something else.

Ultimately, having looked at the claims, having looked at the specification, and having looked at how they changed the prosecution history from the provisional application to the non-provisional application, the answer is, the buffer is consistently treated as a separate component, and it should be identified that way.

I know that Mr. Chen in his slides, on his Slide 27, he referenced our Paragraph 4 notice letter, and he

:33:55 said, well, they never said that the buffer is a separate
:34:00 component in the notice letter. Well, let's look at what we
:34:03 did say.
:34:05 We said the term buffer would be construed to
:34:08 mean an excipient that is added to the composition to
:34:11 maintains the pH. Added to the composition is the same
:34:18 thing as it's a separate component. You add a separate
:34:21 component of a buffer to the composition.
:34:26 We did say that a buffer is a separate an
:34:29 distinct component. That's what the added language means in
:34:34 our notice letter.
:34:38 This will be a little shorter. I will move to
:34:40 the second half of our proposed construction on buffer. It
:34:43 will only be a couple slides here, as we discussed.
:34:47 Again, the second half of our construction is
:34:49 that the buffer has to have a capacity to be a buffer,
:34:55 effectively. It's the common-sense point that a buffer has
:34:58 to have the capacity to maintains the pH throughout the
:35:01 shelf life of the product. And there are a couple of
:35:04 pertinent quotes, not just the one that Mr. Chen
:35:07 highlighted.
:35:07 Let's start on our Slide 29, with a quote from
:35:12 the bottom of Column 1 of the patent, that says, By
:35:16 providing ready-to-use, pre-mixed pharmaceutical
:35:20 compositions with a buffered pH, these pharmaceutical

compositions are stable at room temperature for at least one year.

That's telling us that when they came up with the bag product, it needs to have a buffer, a buffer pH that has the capacity to keep the product stable for whatever the shelf life is of the product. Here they say it's one year. If you look at that time claim language, sometimes it says three months, stable for three months, sometimes it says one year. However they choose to define the shelf life of their product in the patent, it could be, I believe the specification, as you noted earlier, it refers to six months, in these comparable compositions. That is defining the shelf life.

What Column 1 is saying is that the compositions have a buffer with the capacity to maintain the pH for whatever the shelf life is to keep the product stable.

And our Slide 30, this is the quote that Mr. Chen pulled up earlier, about exactly where that language came from. It says, as our construction reads, it has sufficient buffering -- The buffer has sufficient buffering capacity to maintain the pH throughout shelf life.

He is correct, it starts with some embodiments. That's a phrase we see commonly in patents that gets thrown around. If you look at all the embodiments, all the embodiments have a buffer, and all the embodiments, as I

understand it, are intended to be stable for the shelf life of the product. And the buffer, if you look at the full context of the patent, what the patent claims is that the buffer is there to provide that pH control. That's the point of it. And the pH control, for instance, if you look at figures, like Figure 2A and 2B of the patent, the figures are saying that pH control is key. You have to maintain, Figure 2A I believe says you have to maintain the buffered pH, the pH at a certain range to avoid having an unacceptable loss of the amount of product. And Figure 2B says you look at that pH range to make sure there is not an unacceptable amount of impurities in the product.

That pH control is important. That is common sense. That is why you use a buffer in the first place. And all of the embodiments are using the buffer for that pH control. Even though it says some embodiments, there aren't other embodiments that don't have the buffer in them.

So ultimately, common sense should prevail here, that looking at the specification, which says that the buffer has sufficient buffered capacity to maintain a pH, that is part of the construction of how the patents defined the buffer, and it should be part of the construction that is adopted by the Court.

THE COURT: Thank you, Mr. Blake.

MR. BLAKE: Your Honor, we will skip right

forward, we will go to our Slide 43 and talk about "at room temperature."

This limitation, as we stated earlier, doesn't need a construction. Why do they want to construe it? I think Mr. Chen made a reference to it. Whereas buffer is an infringement issue, the one year at room temperature is an invalidity issue. They want to add this idea that it's full term in there. I know he said, well, we can evaluate later whether the prior art says it's full term or it's not.

THE COURT: Both of you, I think at the end of the day, invalidity and infringement has nothing to do with what I am doing. So we are both clear that.

MR. BLAKE: Agreed. I am hoping to get some context as to why we are here.

THE COURT: Especially those of us who do a lot of this work, we know that there is a hidden agenda. That is what I am saying.

MR. BLAKE: Let me jump into -- the full-term aspect of the construction is what's added. We don't think it needs to be added. That's because the full term would exclude what they did in the patent, which in the patent they use accelerated studies that would be an indicator of whether something is stable for one year or three months. And that's why full term is not appropriate. If you look to our Slide 45, there is a quote here directly out of Column

17, which is one of the examples in the patents, and it says, Based on the accelerated stability data, these products would be stable at room temperature for at least 12 months.

And it's looking to this accelerated data to determine -- it's an indicator of the stability over the 12-month period that ultimately is what went into the claims, using the accelerated data.

Adding the concept of it would be stable full term for one year would read out this example, or would be contrary to this example and the examples in the patent that are relying on the accelerated data.

That is why the term full term isn't necessary. If you look at what they did in the patent -- I will look again at another one, on Slide 46, that comes from Columns 15 and 16 of the patent. And again there, they are looking at accelerated data as an indicator of whether you have stability over the one year or three months or however they choose to claim, whatever the shelf life of the product is.

And accelerated data, I am going to Slide 47, again, here in Column 16, they are using accelerated temperature studies. That's because they are an indicator of room temperature stability over a longer period of time. And the phrase is one year at room temperature or three months at room temperature that are in the claims shouldn't

:41:31 **be limited by this idea of full term because it's contrary**
:41:35 **to what was discussed in the patent.**
:41:38 **As I understand it, the primary argument that**
:41:43 **Chiesi relates to why you need to add full term is this**
:41:47 **Connors reference that is cited on our slide. Mr. Chen made**
:41:54 **reference to it. Right after the sentence is that discusses**
:41:56 **accelerated testing, they cite the Connors reference in the**
:42:01 **patents. And that Connors reference is incorporated by**
:42:05 **reference.**
:42:06 **Mr. Chen says if you look at the Connors**
:42:08 **reference it says you got to have full-term studies.**
:42:12 **Our Slide 48 has put up the relevant language**
:42:15 **out of the Connors reference. There is three sentences here**
:42:21 **that are relevant. The last sentence is the one Chiesi is**
:42:25 **relying on. The last sentence says, all these revisions and**
:42:29 **changes should be confirmed with full-term studies. But you**
:42:33 **need to back up to the previous two previous sentences,**
:42:37 **which say, accelerated studies are perfectly acceptable.**
:42:40 **They are an indicator of stability for one year at room**
:42:44 **temperature or stability at three months of room**
:42:47 **temperature. It says short-term accelerated studies should**
:42:50 **be carried out. And comparison of these data under**
:42:54 **accelerated conditions is the key at this stage in**
:42:57 **determination the effect that a revision has on stability in**
:43:01 **a short time.**

:43:02 **And Mr. Chen made reference to, and I want to**
:43:04 **make sure I am clear for the Court when I stated earlier, we**
:43:07 **do have a short declaration in our reply brief. It's not**
:43:11 **related to the construction of terms. It is limited to only**
:43:15 **five pages that say this is used in the art, this type of**
:43:18 **accelerated testing is used in the art. It is common and**
:43:22 **the FDA expects it.**
:43:24 **Frankly, if you construed everything by throwing**
:43:26 **out the extrinsic evidence, you wouldn't need any of it.**
:43:30 **THE COURT: Which is typically my practice.**
:43:32 **MR. BLAKE: That's why I pointed that out.**
:43:33 **THE COURT: Unless we were talking about --**
:43:36 **certainly, when it comes to experts, if we are talking about**
:43:39 **other types of extrinsic evidence, like dictionary**
:43:42 **definitions and the like, we all know what Phillips has to**
:43:48 **say about that. I am going to follow the canons of**
:43:51 **construction.**
:43:53 **MR. BLAKE: That's pretty much all I have on the**
:43:55 **at room temperature. I think it's a straightforward point,**
:43:58 **that construction is not necessary.**
:44:00 **At the risk of getting myself in trouble, I will**
:44:02 **make one last statement about premixed and then get out of**
:44:06 **the way. That is just to answer one of your points earlier**
:44:08 **about what's our concern with this -- I know where you are**
:44:11 **leaning -- but what's our concern with the stability**

:44:14 **language. It's that it's separately recited in the claims.**
:44:17 **If you look as them, the claims have separate language about**
:44:20 **the stability, and it becomes confusing when you look at the**
:44:22 **claims separately referring to that it has to be one year at**
:44:26 **room temperature, over one year at room temperature you**
:44:32 **can't have more than ten percent of lost of nicardipine or**
:44:35 **more than three percent of impurities develop, or other**
:44:39 **claims say over three months you can't have more than ten**
:44:41 **percent loss and more than three percent developing**
:44:45 **impurities.**
:44:46 **That is a stability limitation in those claims.**
:44:48 **Then adding it to pre-mix, specifically, it refers to six**
:44:51 **months. It starts to lead to the possibility of**
:44:53 **inconsistencies in the claim language.**
:44:56 **That is the biggest concern for us, is to not**
:44:59 **have confusion on that front.**
:45:02 **THE COURT: Do we have a civil action number of**
:45:06 **Judge Hillman's case?**
:45:08 **MR. BLAKE: I sure do.**
:45:11 **MR. CHEN: It is in our slide deck, Your Honor.**
:45:25 **Slide 17, Your Honor, of plaintiffs' slide deck.**
:45:30 **THE COURT: Thank you.**
:45:31 **Mr. Chen, your reply.**
:45:35 **Thank you, Mr. Blake.**
:45:37 **MR. BLAKE: Thank you, Your Honor.**

:45:38 **MR. CHEN: Your Honor for the Court's**
:45:44 **information, the action in the related case before Judge**
:45:48 **Hillman is 13-05723, in New Jersey.**
:45:55 **Your Honor, with respect to the buffer terms, I**
:45:59 **guess I lost track of how many times I heard the word**
:46:02 **"separately," but it wasn't in the notice letter, separate**
:46:05 **and distinct. And that much is clear.**
:46:08 **You heard from counsel that a pH adjuster and a**
:46:12 **buffer is an opposite. If we are going to go down that**
:46:17 **path, and that goes to the liability phase of the case, Your**
:46:20 **Honor, I would submit that that requires some fact-finding.**
:46:23 **That issue was not set forth in the papers. Obviously, we**
:46:27 **disagree that pH adjusters and buffers are opposite. I**
:46:33 **think that this is more appropriate for the experts to weigh**
:46:36 **in on.**
:46:37 **But just in response to, I guess, the attorney**
:46:41 **argument from the other side on this issue, what happens**
:46:45 **with the pH adjuster is it changes the pH by changing the**
:46:52 **ratio pH of different charged species in the solution. Then**
:46:54 **at a given pH, if you decide to stop there and test it, it**
:46:58 **may have a buffering capacity, buffering potential based on**
:47:01 **that change in the ratio of the charged species.**
:47:04 **So they are very much interrelated, and they are**
:47:06 **not opposites. There is nothing in the record to support**
:47:08 **that.**

There is also nothing in the specification that says a buffer is separate and distinct from a pH adjuster. Those words just are not anywhere in the intrinsic evidence.

With respect to the '405 patent, I would just point out that it is referred to in our patent. It is a different patentee. I believe it's Syntex.

I am not sure what they meant when they called things, certain things unsatisfactory. My understanding of those examples, it's the concentrated version of nicardipine, which was the version that we disclaimed and distinguished over. It is not the premixed solution.

And with respect to throughout the shelf life, again, clearly, only referring to in some embodiments. I think what you have to look at, though, is whether the pH needs to be necessarily maintained throughout the shelf life. And there is nothing in the patent that says the full scope of the claim should be limited to just those embodiments. There was no disavowal, and the patentee is entitled to the full breadth of the claim.

As an example, if the product is stable for one year there is nothing in the patent that says the pH can maybe slip after ten and a half months, 11 months or something like that. It still maintains the stability limitations.

That is why it would be wrong to limit the scope

of the claims so that the pH itself has to be maintained throughout the entire shelf life of the product.

One other note, Your Honor.

As far as separately and distinctly allegedly listing in the claims, Claim 1 doesn't refer to a pH adjuster. I saw the slide that they referred to Claim 2 that says that the pH adjuster is further comprising pH adjusters selected from the group of this type of acid and sodium hydroxide. That claim, Claim 2, is setting forth the limited universe from which you can pick a pH adjuster.

So there is nothing in the claims to support that they are separate and distinct.

As to room temperature, maybe I spoke too quickly, Your Honor, that there is no dispute. I gather, when counsel says that our construction would exclude the examples, that that somehow means that one year should be interpreted to be something less than 12 months. That's why I think there is a fundamental disagreement. I don't think the parties disagree that you can model or hypothesize full term using accelerated additions. That's for the liability phase.

The question is claim construction here, what does the word one year mean? And in our view, it means a full one year and nothing less.

Whether you want to show or use some type of

accelerated means later on in the liability phase is a separate issue.

Lastly, as to the term premixed, I think I tried to make this clearly earlier in the presentation. But apparently there was some confusion.

Our view of the word stable in the Patent Office's claim construction is taken from, the Patent Office says this in the footnote stated in Column 3, Lines 51 to 53, that stability refers to the overall stability of the product, the shelf life of the product, how long can it keep the composition on the shelf and safely administer it to a patient.

The claim limitations only focus on two aspects, the concentration of the drug, nicardipine, how much it decreases over time, and the total impurities. Those are two aspects of the overall stability. But there is other components to a drug's overall stability, particulate matter, color, et cetera.

That is it. Thank you, Your Honor.

THE COURT: All right, counsel.

MR. BLAKE: Your Honor --

THE COURT: No.

I will be getting an order out in give or take 30 days.

Is there anything while you are here that you

need to discuss with me?

MR. CHEN: From plaintiffs, not at the moment. There are some percolating discovery issues. But I think we will raise them when the time is appropriate.

THE COURT: When they are ripe, we will talk about them. Hopefully not.

Safe travels.

MR. BLAKE: Thank you, Your Honor.

(Hearing concluded at 10:56 a.m.)

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Reporter: Kevin Maurer